INSTRUCTION OF RHEUMATOID FACTOR

ASSAY KIT BY LATEX ENHANCED IMMUNOTURBIDIMETRY METHOD

[PRODUCT NAME]

Rheumatoid Factor (RF) Assay Kit by Latex Enhanced Immunoturbidimetry Method.

[Packing specifications]

Basing on the bottle type, product model can be classifie d into 7170, 7060, 7020, Beckman, Toshiba, Mindray, Du pont, Innova, Siemens, KHB, Abbott, General type, etc.

R1：40ml×1	R2：10ml×1	R1：20ml×1	R2：5ml×1
R1：40ml×2	R2：20ml×1	R1：40ml×3	R2 :30ml×1
R1：40ml×4	R2：40ml×1	R1：60ml×3	R2 :45ml×1
R1：90ml×2	R2：45ml×1	R1：40ml×4	R2 :20ml×2
R1：40ml×8	R2：20ml×4	R1：40ml×8	R2 :40ml×2
R1：60ml×9	R2：45ml×3	R1：6×60T	R2：6×60T
R1：12×60T	R2：12×60T	R1：1×310T	R2 :1×310T
R1：2×310T	R2：2×310T	R1：3×310T	R2 :3×310T
R1：4×310T	R2：4×310T	R1：8×310T	R2 :8×310T

[Intended Use]

This product is used to determine RF content in human serum.

[PRINCIPLE]

Rheumatoid Factor (RF) is an immunoglobulin (antibody) anti-human denatured IgG that mainly occur in patients with rheumatoid arthritis. RF bind to Fc fragment of denture IgG. The RF in human sample meets the latex particles pre-coated with denatured IgG in the liquid buffer, forming antigen-antibody complex, and the turbidity formed is proportional to the RF concentration in the linear range. RF concentration in the sample can be calculated by comparing the calibrator result with same processing.

[REAGENT COMPOSITION]

R1:

Tris buffer	100mmol/L
PEG, preservatives	appropriate

R2:

Tris buffer	
Preservatives	
Latex particle suspensions	appropriate

Calibrator & Control Optional

Calibrator：1.0ml×1；Control：0.5ml×1

[Storage And Stability]

Stored for up to 12 months at 2-8°C, protect from light. After opening, the reagent remains stable for 28 days at 2-8°C, protect from light.

[Applicable Instrument]

This assay kit is suitable for automatic or semi-automatic biochemical analyzer with 600nm wavelength.

［Sample Requirements］

The sample should be human serum (without haemolysis). Samples testing should be completed at the same day after collected. Otherwise, the samples should be cryopreserved and avoid repeated freeze-thaw cycles. RF in the samples remain stable for 7 days at 2-8°C or for 3 months at cryopreservation condition.

［Test Method］

1. Basic parameters:

Method: End assay Temperature: 37°C

Primary wavelength: 600nm Secondary wavelength: none

Sample volume: 4μl R1: 240μl

R2: 60μl Response direction: Positive

Calibration method: Multi-point calibration

2. Assay Procedure

	Blank(B)	Sample(U)	Calibrator (Ci)
ddH_2O (μl)	4	—	—
Sample (μl)	—	4	—
Ci (μl)	—	—	4
R1 (μl)	240	240	240
Mix well, incubate at 37°C for 3-5 min.			
R2 (μl)	60	60	60

Mix well, incubate for 30 sec. Take blank well as zero and measure the absorbance value A1, 4.5 min later measure the absorbance value A2.

Calculate ΔA＝A2-A1

ASSAY PROCEDURE SUMMARY

Temperature：37°C Primary wavelength 600nm

Secondary wavelength: none

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R1: 240μl R2: 60μl

Sample: 4μl

3. Calculations：

Based on multi-point calibrator concentration and the corresponding absorbance change rate ΔA/min, the multi-point non-linear calibration model is used to define the working curve, sample absorbance change rate on the working curve with the corresponding concentration is concentration of sample.

[Reference Range]

0IU/ml -30IU/ml

Recommendations: Each laboratory should establish its own reference range.

[Explanation for the test result]

1. The test results reflect only the status at the sampling time. Clinicians need to be combined with clinical data and other relevant test results to make judgment.

2. There is no significant effect on the test result when the sample contains Ascorbic acid≤0.5g/L; Bilirubin≤0.5g/L; Hemoglobin ≤5.0g/L; Triglycerides ≤10g/L.

[Test Method Limitations]

Dilute with physiological saline and multiply the result by the dilution factor when the concentration of RF is over 160IU/ml.

[Product Performance]

1. DETECTION RANGE: 5IU/ml-160IU/ml, r≥0.99.
2. PRECISION: Intra-assay CV≤5%, Inter-assay CV≤10%.
3. ACCURACY: Inaccuracy≤10%
4. Blank absorbance: 0.3 ≤ the absorbance value ≤1.5 when at 600nm wavelength and optical path 10mm.

[PRECAUTIONS]

1. For in vitro diagnostic use only.
2. The reagent becomes cloudy , blank absorbance value>1.500 or absorbance value <0.300, should be discarded.
3. The reagent and sample amount can be changed with same ratio according to needs.
4. The test equipment must be clean to avoid contamination.
5. Reagents and components of different batches are not interchangeable.
6. The waste solution generated by the test and decomposition difficultly packaging materials should be collected and sent to local waste treatment station.

[Reference]

Yingwu Ye et al. National Guide to Clinical Laboratory Procedures (Third Edition). Southeast University Press, 2006: 651-653.

[MANUFACTURER]

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[Product standards]

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